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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,206	07/27/2000	Jane A. Gross	98-75C2	1238

7590 04/28/2003

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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	17

DATE MAILED: 04/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/627,206	GROSS, JANE A.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the c ver sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89-116* is/are pending in the application.

4a) Of the above claim(s) *90-101 and 112-116* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89 and 102-111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment and response filed on 2-10-2003 are acknowledged. Claims 105-106 and 110-111 are amended. Claims 102-111 are currently under examination.

This application contains claims 90-101 and 112-116 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections Withdrawn

The rejection of claims 105-106 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "the composition comprises a multimer of fusion proteins" is withdrawn in light of the amendment thereto.

The rejection of claims 111-112 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "the composition comprises a dimer of fusion proteins" is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 89-102-111 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 64-96 of copending Application No. 569,245 is maintained for reasons of record.

Applicant argues:

1. All pending claims are drawn to methods of inhibiting B lymphocyte proliferation in a mammal whereas the claims of the copending application are drawn to methods of inhibiting BLyS activity in a mammal.

Applicant's arguments have been fully considered and deemed to be unpersuasive. The methods of the two applications utilize the same compositions and method steps and hence would have the same effect on the mammal (i.e. the inhibition of B lymphocyte proliferation **and** inhibition of BLyS activity).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The instant claims are drawn to methods of inhibiting B cell proliferation by the administration of a soluble form the ztnf4 receptor (TACI). Said soluble form of the ztnf4 receptor can comprise the extracellular domain of the TACI protein and may be optionally fused to the heavy chain constant region of human immunoglobulins.

The rejection of claims 89, 102 and 107 under 35 U.S.C. 102(a) as being anticipated by Bram et al. (WO 98/39361 – IDS-5) is maintained for reasons of record.

Applicant argues:

1. The instant invention requires binding to the ligand ztnf4.

2. Bram et al. do not disclose the identity of the endogenous ligand of the TACI protein.

Applicant's arguments have been fully considered and deemed non-persuasive.

Since compositions (i.e. ztnf4 receptor protein) disclosed by Bram et al. are identical to those of the instant invention, said compositions would possess all of the same properties as those of the instant invention (including the ability to bind ztnf4) and hence are deemed to be functional equivalents. Hence, Bram et al. anticipates all the limitations of the rejected claims. As outlined previously, Bram et al. disclose the use of genetically engineered constructs to regulate B-cell activity through its interaction with cellular receptor ligands (i.e. ztnf4). Said constructs can consist of the extracellular domain of the TACI receptor fused to the Fc domain of an

immunoglobulin (see page 24, lines 24-26). Bram et al. further disclose that said extracellular domain has an amino acid sequence corresponding to about residue 1 to about residue 166 of the consensus sequence of TACI and that the ligand binding region is a sub-fragment of the extracellular domain (see page 18, lines 27-30).

The rejection of claims 89, 102 and 107 under 35 U.S.C. 102(a) as being anticipated by Bram et al. (U.S. Patent 5,969,102 – IDS-5) is maintained for reasons of record.

Bram et al. disclose the use of genetically engineered constructs to regulate B-cell activity through its interaction with cellular receptor ligands (i.e. ztnf4). Said constructs can consist of the extracellular domain of the TACI receptor fused to the Fc domain of an immunoglobulin (see page 24, lines 24-26). Bram et al. further disclose that said extracellular domain has an amino acid sequence corresponding to about residue 1 to about residue 166 of the consensus sequence of TACI and that the ligand binding region is a sub-fragment of the extracellular domain (see page 18, lines 27-30).

It should be noted that Applicant has failed to address this rejection in his response.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The instant claims are drawn to methods of inhibiting B cell proliferation by the administration of a soluble form the ztnf4 receptor (TACI). Said soluble form of the ztnf4 receptor can comprise the extracellular domain of the TACI protein that is optionally fused to the heavy chain constant region of human immunoglobulins. Additionally, said soluble form of the ztnf4 may comprise a dimmer or other multimer of said fusion protein

The rejection of claims 89 and 102-111 under 35 U.S.C. 103(a) as being unpatentable over Bram et al. (WO 98/39361 – IDS-5), as cited above, in view of Presta et al. (U.S. Patent 5,739,277) is maintained for reasons of record.

Applicant argues:

1. The instant invention requires binding to the ligand ztnf4.
2. Bram et al. do not disclose the identity of the endogenous ligand of the TACI protein.
3. The disclosure by Presta et al. is insufficient to overcome the aforementioned deficiency.

Applicant's arguments have been fully considered and deemed non-persuasive.

Since compositions (i.e. ztnf4 receptor protein) disclosed by Bram et al. are identical to those of the instant invention, said compositions would possess all of the same properties as

those of the instant invention (including the ability to bind ztnf4) and hence are deemed to be functional equivalents. As outlined previously, Bram et al. disclose the use of genetically engineered constructs to regulate B-cell activity through its interaction with cellular receptor ligands (i.e. ztnf4). Said constructs can consist of the extracellular domain of the TACI receptor fused to the Fc domain of an immunoglobulin (see page 24, lines 24-26). Bram et al. further disclose that said extracellular domain has an amino acid sequence corresponding to about residue 1 to about residue 166 of the consensus sequence of TACI and that the ligand binding region is a sub-fragment of the extracellular domain (see page 18, lines 27-30). Bram et al differs from the instant invention (claims 103-104 and 108-109) in that they do not disclose the specific use of human IgG1 heavy chains in fusion proteins. Presta et al. disclose methods of making fusion proteins comprising the Fc portion of a human immunoglobulin (including IgG1) and the advantages of making such proteins. Consequently, it would have been obvious to one of ordinary skill in the art to utilize the Fc portion of a human IgG1 molecule of Presta et al. in the fusion protein disclosed by Bram et al. in order to take care of the increased circulatory half life of said fusion proteins as disclosed by Presta et al. (see abstract). One would have had a high expectation of success since Presta et al. disclose that the Fc portions of the various immunoglobulins can be used interchangeably (see column 7, lines 3-45). Additionally, it would have been obvious to one of ordinary skill in the art to use said fusion protein in multimer form to increase the number of binding sites on the soluble form of the receptor.

New Grounds of Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 105-106 and 110-111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 105-106 are rendered vague and indefinite by the use of the phrase "the composition comprises multimeric proteins comprising one or more fusion proteins". It is unclear how one fusion protein can be a multimeric protein.

Claims 110-111 are rendered vague and indefinite by the use of the phrase "the composition comprises dimeric proteins comprising one or more fusion proteins". It is unclear how one fusion protein can be a dimeric protein.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Robert A. Zeman
April 23, 2003